

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Prayaga *et al.*
 ASSIGNEE: CuraGen Corporation
 SERIAL NUMBER: 09/679,740 EXAMINER: Not Yet Assigned
 FILING DATE: October 5, 2000 ART UNIT: Not Yet Assigned
 FOR: ENDOZEPINE-LIKE POLYPEPTIDES AND POLYNUCLEOTIDES ENCODING SAME

January 22, 2001
Boston, Massachusetts

Assistant Commissioner for Patents
Washington, D.C. 20231

TRANSMITTAL LETTER

Sir:

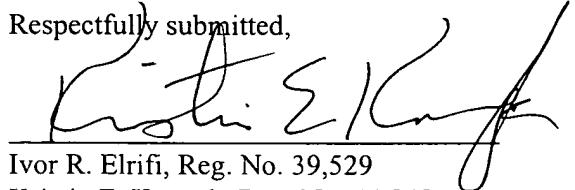
Transmitted herewith for filing in the present application are the following documents:

- Information Disclosure Statement (4 pages);
- Modified Form 1449/PTO (3 pages) in duplicate;
- Copies of Cited references A1 and C1-C38;
- Return Postcard

No fee is believed to be due at this time. However, the Commissioner is hereby authorized to charge any additional fees that may be due to Deposit Account No. 50-0311, Reference No. 15966-75B (CURA-75B). A duplicate copy of this transmittal letter is enclosed.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at 617/542-6000, Boston, Massachusetts.

Respectfully submitted,


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DATE: January 22, 2001



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INFORMATION DISCLOSURE STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants hereby make of record the documents listed below and on the attached modified Form PTO-1449 (submitted in duplicate) in the above-identified application, copies of which are submitted herewith. The order of presentation of the references should not be construed as an indication of the importance of the references.

U.S. Patent Documents:

A1 5,734,038 3/31/98 Au-Young, et al.

Other Prior Art – Non Patent Literature Documents:

- C1 Adams, et al., 2000 "The genome sequence of *Drosophila melanogaster*." Science 287: 2185-2195. GenBank Accession Number: **q9VLS4**
- C2 Anholt, R. R., P. L. Pedersen, et al. (1986). "The peripheral-type benzodiazepine receptor. Localization to the mitochondrial outer membrane." J Biol Chem 261(2): 576-83.
- C3 Burton, J. 2000 Direct Submission. GenBank Accession Number: **AL121672**
- C4 Chen, et al., 1988 "Isolation and characterization of procine diazepam-binding inhibitor, a polypeptide not only of cerebral occurrence but also common in intestinal tissues and with effects on regulation of insulin release." Eur. J. Biochem. 174 (2): 239-245. GenBank Accession Number: **p12026**
- C5 DeBernardi, M. A., R. R. Crowe, et al. (1988). "Chromosomal localization of the human diazepam binding inhibitor gene." Proc Natl Acad Sci U S A 85(17): 6561-5.
- C6 Geisbrecht, et al., 1999 "Characterization of PECI, a Novel Monofunctional D3, D2-Enoyl-CoA Isomerase of Mammalian Peroxisomes. J. Biol. Chem. (In press) GenBank Accession Number: **af153612**
- C7 Geisbrecht, et al., 1999 "Characterization of PECI, a Novel Monofunctional D3, D2-Enoyl-CoA Isomerase of Mammalian Peroxisomes." J. Biol. Chem. (In press) GenBank Accession Number: **af153613**
- C8 Gersuk, V. H., T. M. Rose, et al. (1995). "Molecular cloning and chromosomal localization of a pseudogene related to the human acyl-CoA binding protein/diazepam binding inhibitor." Genomics 25(2): 469-76.

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- C9 Gracey, et al. 1998 "The detection of cold-induced gene expression in carp liver by differential display RT-PCR." Direct Submission. GenBank Accession Number: **af006493**
- C10 Gray, et al. 1986 "Cloning and expression of cDNA for human diazepam binding inhibitor, a natural ligand of an allosteric regulatory site of the gamma-aminobutyric acid type A receptor." Proc. Natl. Acad. Sci. U.S.A. 83 (19): 7547-7551. GenBank Accession Number: **m14200**
- C11 Gray, P. W., D. Glaister, et al. (1986). "Cloning and expression of cDNA for human diazepam binding inhibitor, a natural ligand of an allosteric regulatory site of the gamma- aminobutyric acid type A receptor." Proc Natl Acad Sci U S A 83(19): 7547-51.
- C12 Gray, P.W. 1987 "Molecular biology of diazepam binding inhibitor." Neuropharmacology 26: 863-865. GenBank Accession Number: **m20268**
- C13 Hamers, et al. 1996 "Variable fragments of immunoglobulins – use for therapeutic or veterinary purposes." Patent: WO 9634103. GenBank Accession Number: **a57711**
- C14 Ivell, R., et al. 2000 "Progressive inactivation of the haploid expressed gene for the sperm-specific endozepine-like peptide (ELP) through primate evolution." Gene 255 (2): 335-345. GenBank Accession Number: **AF229804**
- C15 Kato, K. 1993 "Sequence analysis of twenty mouse brain cDNA clones selected by specific expression patterns." J. Neurosci. (In Press) GenBank Accession Number: **x61431**
- C16 Kolmer, et al. 1994 "Tissue-specific expression of the diazepam-binding inhibitor in *Drosophila melanogaster*: cloning, structure, and localization of the gene." Mol. Cell. Biol. 14: 6983-6995. GenBank Accession Number: **u04823**
- C17 Kragelund, et al. 1996 "Fast and one-step folding of closely and distantly related homologous proteins of a four-helix bundle family." J. Mol. Biol. 256 (1): 187-200. GenBank Accession Number: **s63593**
- C18 Kragelund, et al. 1996 "Fast and one-step folding of closely and distantly related homologous proteins of a four-helix bundle family." J. Mol. Biol. 256 (1): 187-200. GenBank Accession Number: **s63594**
- C19 Kragelund, et al., 1996 "Fast and one-step folding of closely and distantly related homologous proteins of a four-helix bundle family." J. Mol. Biol. 256:187-200. GenBank Accession Number: **q9PRL8**
- C20 Lagueux, et al. 1997 "Diazepam binding inhibitor/endozepine/acyl-CoA-binding homologue from *Drosophila melanogaster*." Unpublished. GenBank Accession Number: **x75596**
- C21 Lihrmann, et al. 1994 "Frog diazepam-binding inhibitor: Peptide sequence, cDNA cloning and expression in the brain." Proc. Natl. Acad. Sci. U.S.A. 91: 6899-6903. GenBank Accession Number: **RRU09205**
- C22 Mandrup, et al. 1991 "Gene synthesis, expression in *Escherichia coli*, purification and characterization of the recombinant bovine acyl-CoA-binding protein." Biochem. J. 276 (pt. 3): 817-823. GenBank Accession Number: **CAA44618**
- C23 McDougall, et al. 1999 Direct Submission. GenBank Accession Number: **al096874**
- C24 NCI-CGAP: National Cancer Institute, Cancer Genome Anatomy Project. GenBank Accession Number: **AA877351**
- C25 Orian, et al. 1988 "Cloning and sequencing of the ovine growth hormone gene." Nucleic Acids Res. 16 (18): 9046. GenBank Accession Number: **ab017920**
- C26 Owens, et al. 1989 "Sequence and expression of the murine diazepam binding inhibitor." Brain Res. Mol. Brain. Res. 6 (2-3): 101-108. GenBank Accession Number: **p31786**
- C27 Pusch, et al. 1996 "A novel endozepine-like peptide (ELP) is exclusively expressed in male germ cells." Mol. Cell. Endocrinol. 122 (1) 69-80. GenBank Accession Number: **O09035**
- C28 Ricke, et al. 1998 "Sequencing of Human Chromosome 16p13.3." Unpublished. GenBank Accession Number: **AC005736**
- C29 Rose, et al. 1994 "Nucleotide sequence and genomic structure of a duck acyl-CoA binding prote/diazepam-binding inhibitor: co-localization with S-acyl fatty acid synthase thioesterase." DNA Cell Biol. 13 (6): 669-678. GenBank Accession Number: **p45882**
- C30 Rose, T. M., E. R. Schultz, et al. (1992). "Molecular cloning of the gene for the yeast homolog (ACB) of diazepam binding inhibitor/endozepine/acyl-CoA-binding protein." Proc Natl Acad Sci U S A 89(23): 11287-91.
- C31 Todd, S. and S. L. Naylor (1992). "New chromosomal mapping assignments for argininosuccinate synthetase pseudogene 1, interferon-beta 3 gene, and the diazepam binding inhibitor gene." Somat Cell Mol Genet

APPLICANTS: Shimkets *et al.*
U.S.S.N.: 09/679,740

- 18(4): 381-5.
- C32 Waterston, R.H. 2000 "The sequence of Homo sapiens clone." Unpublished. GenBank Accession Number: **AC025743**
- C33 Webb, et al. 1987 "Bovine and human cDNA sequences encoding a putative benzodiazepine receptor ligand." DNA 6 (1): 71-79. GenBank Accession Number: **p07107**
- C34 Webb, et al. 1987 "Bovine and human cDNA sequences encoding a putative benzodiazepine receptor ligand." DNA 6 (1): 71-79. GenBank Accession Number: **p07108**
- C35 Webb, et al. 1987 "Bovine and human cDNA sequences encoding a putative benzodiazepine receptor ligand." DNA 6 (1): 71-79. GenBank Accession Number: **m15888**
- C36 Webb, et al. 1987 "Bovine and human cDNA sequences encoding a putative benzodiazepine receptor ligand." DNA 6 (1): 71-79. GenBank Accession Number: **m15887**
- C37 Webb, et al. 1987 "Bovine and human cDNA sequences encoding a putative benzodiazepine receptor ligand." DNA 6 (1): 71-79. GenBank Accession Number: **m15886**
- C38 Webb, N. R., T. M. Rose, et al. (1987). "Bovine and human cDNA sequences encoding a putative benzodiazepine receptor ligand." DNA 6(1): 71-9.

This Information Disclosure Statement is being filed:

- within three months of the filing date of the National Application;
- within three months of the filing date of the entry of the National Stage, as set forth in 37 C.F.R. §1.491, in an International Application; or
- before the mailing date of a first Office Action on the merits in the above-identified case.

Accordingly, no fee or certification is required. 37 C.F.R. §1.97

A copy of each of the above-identified information is enclosed unless otherwise indicated on the attached Form PTO-1449 (modified). It is respectfully requested that the Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims, and signs the enclosed form PTO-1449 to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application.

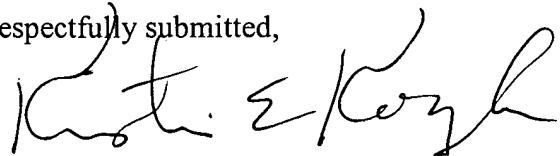
By submitting this Information Disclosure Statement, the Applicant makes no representation that: (1) a search has been performed, of the extent of any search performed, or that more relevant information does not exist; (2) the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b); and (3) the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his/her own conclusion regarding the relevance of the cited information. An early and favorable action

APPLICANTS: Shimkets *et al.*
U.S.S.N.: 09/679,740

is hereby requested. Please charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. CURA-75B (15966-575B).

Respectfully submitted,



Ivor R. Elrifi, Reg. No. 39,529
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Dated: January 22, 2001

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Page 1 of 3

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Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Modified Form 1449/PTO		Application Number	09/679,740
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Filing Date	10/5/2000
(use as many sheets as necessary)		First Named Inventor	Prayaga et al.
		Group Art Unit	Not Yet Assigned
		Examiner Name	Not Yet Assigned
		Attorney Docket Number	15966-575B (Cura-75B)

U.S. PATENT DOCUMENTS							
Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
	A1	5,734,038	3/31/98	Au-Young, et al.			

FOREIGN PATENT DOCUMENTS							
Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)		Date of Publication	Translation Yes No	
	B1						

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C1	Adams, et al., 2000 "The genome sequence of <i>Drosophila melanogaster</i> ." <u>Science</u> 287: 2185-2195. GenBank Accession Number: q9VLS4
	C2	Anholt, R. R., P. L. Pedersen, et al. (1986). "The peripheral-type benzodiazepine receptor. Localization to the mitochondrial outer membrane." <u>J Biol Chem</u> 261(2): 576-83.
	C3	Burton, J. 2000 Direct Submission. GenBank Accession Number: AL121672
	C4	Chen, et al., 1988 "Isolation and characterization of procine diazepam-binding inhibitor, a polypeptide not only of cerebral occurrence but also common in intestinal tissues and with effects on regulation of insulin release." <u>Eur. J. Biochem.</u> 174 (2): 239-245. GenBank Accession Number: p12026
	C5	DeBernardi, M. A., R. R. Crowe, et al. (1988). "Chromosomal localization of the human diazepam binding inhibitor gene." <u>Proc Natl Acad Sci U S A</u> 85(17): 6561-5.
	C6	Geisbrecht, et al., 1999 "Characterization of PECI, a Novel Monofunctional D3, D2-Enoyl-CoA Isomerase of Mammalian Peroxisomes. J. Biol. Chem. (In press) GenBank Accession Number: af153612
	C7	Geisrecht, et al., 1999 "Characterization of PECI, a Novel Monofunctional D3, D2-Enoyl-CoA Isomerase of Mammalian Peroxisomes." <u>J. Biol. Chem.</u> (In press) GenBank Accession Number: af153613
	C8	Gersuk, V. H., T. M. Rose, et al. (1995). "Molecular cloning and chromosomal localization of a pseudogene related to the human acyl-CoA binding protein/diazepam binding inhibitor." <u>Genomics</u> 25(2): 469-76.
	C9	Gracey, et al. 1998 "The detection of cold-induced gene expression in carp liver by differential display RT-PCR." Direct Submission. GenBank Accession Number: af006493
	C10	Gray, et al. 1986 "Cloning and expression of cDNA for human diazepam binding inhibitor, a natural ligand of an allosteric regulatory site of the gamma-aminobutyric acid type A receptor." <u>Proc. Natl. Acad. Sci. U.S.A.</u> 83 (19): 7547-7551. GenBank Accession Number: m14200
	C11	Gray, P. W., D. Glaister, et al. (1986). "Cloning and expression of cDNA for human diazepam binding

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		inhibitor, a natural ligand of an allosteric regulatory site of the gamma- aminobutyric acid type A receptor." <u>Proc Natl Acad Sci U S A</u> 83(19): 7547-51.
	C12	Gray, P.W. 1987 "Molecular biology of diazepam binding inhibitor." <u>Neuropharmacology</u> 26: 863-865. GenBank Accession Number: m20268
	C13	Hamers, et al. 1996 "Variable fragments of immunoglobulins – use for therapeutic or veterinary purposes." <u>Patent: WO 9634103</u> . GenBank Accession Number: a57711
	C14	Ivell, R., et al. 2000 "Progressive inactivation of the haploid expressed gene for the sperm-specific endozepine-like peptide (ELP) through primate evolution." <u>Gene</u> 255 (2): 335-345. GenBank Accession Number: AF229804
	C15	Kato, K. 1993 "Sequence analysis of twenty mouse brain cDNA clones selected by specific expression patterns." <u>J. Neurosci.</u> (In Press) GenBank Accession Number: x61431
	C16	Kolmer, et al. 1994 "Tissue-specific expression of the diazepam-binding inhibitor in <i>Drosophila melanogaster</i> : cloning, structure, and localization of the gene." <u>Mol. Cell. Biol.</u> 14: 6983-6995. GenBank Accession Number: u04823
	C17	Kragelund, et al. 1996 "Fast and one-step folding of closely and distantly related homologous proteins of a four-helix bundle family. <u>J. Mol. Biol.</u> 256 (1): 187-200. GenBank Accession Number: s63593
	C18	Kragelund, et al. 1996 "Fast and one-step folding of closely and distantly related homologous proteins of a four-helix bundle family. <u>J. Mol. Biol.</u> 256 (1): 187-200. GenBank Accession Number: s63594
	C19	Kragelund, et al., 1996 "Fast and one-step folding of closely and distantly related homologous proteins of a four-helix bundle family." <u>J. Mol. Biol.</u> 256:187-200. GenBank Accession Number: q9PRL8
	C20	Lagueux, et al. 1997 "Diazepam binding inhibitor/endozepine/acyl-CoA-binding homologue from <i>Drosophila melanogaster</i> ." Unpublished. GenBank Accession Number: x75596
	C21	Lihrmann, et al. 1994 "Frog diazepam-binding inhibitor: Peptide sequence, cDNA cloning and expression in the brain. <u>Proc. Natl. Acad. Sci. U.S.A.</u> 91: 6899-6903. GenBank Accession Number: RRU09205
	C22	Mandrup, et al. 1991 "Gene synthesis, expression in <i>Escherichia coli</i> , purification and characterization of the recombinant bovine acyl-CoA-binding protein. <u>Biochem. J.</u> 276 (pt. 3): 817-823. GenBank Accession Number: CAA44618
	C23	McDougall, et al. 1999 Direct Submission. GenBank Accession Number: aI096874
	C24	NCI-CGAP: National Cancer Institute, Cancer Genome Anatomy Project. GenBank Accession Number: AA877351
	C25	Orian, et al. 1988 "Cloning and sequencing of the ovine growth hormone gene." <u>Nucleic Acids Res.</u> 16 (18): 9046. GenBank Accession Number: ab017920
	C26	Owens, et al. 1989 "Sequence and expression of the murine diazepam binding inhibitor. <u>Brain Res. Mol. Brain. Res.</u> 6 (2-3): 101-108. GenBank Accession Number: p31786
	C27	Pusch, et al. 1996 "A novel endozepine-like peptide (ELP) is exclusively expressed in male germ cells." <u>Mol. Cell. Endocrinol.</u> 122 (1) 69-80. GenBank Accession Number: O09035
	C28	Ricke, et al. 1998 "Sequencing of Human Chromosome 16p13.3." Unpublished. GenBank Accession Number: AC005736
	C29	Rose, et al. 1994 "Nucleotide sequence and genomic structure of a duck acyl-CoA binding prote/diazepam-binding inhibitor: co-localization with S-acyl fatty acid synthase thioesterase." <u>DNA Cell Biol.</u> 13 (6): 669-678. GenBank Accession Number: p45882
	C30	Rose, T. M., E. R. Schultz, et al. (1992). "Molecular cloning of the gene for the yeast homolog (ACB) of diazepam binding inhibitor/endozepine/acyl-CoA-binding protein." <u>Proc Natl Acad Sci U S A</u> 89(23): 11287-91.
	C31	Todd, S. and S. L. Naylor (1992). "New chromosomal mapping assignments for argininosuccinate synthetase pseudogene 1, interferon-beta 3 gene, and the diazepam binding inhibitor gene." <u>Somat Cell Mol Genet</u> 18(4): 381-5.

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	C32	Waterston, R.H. 2000 "The sequence of Homo sapiens clone." Unpublished. GenBank Accession Number: AC025743
	C33	Webb, et al. 1987 "Bovine and human cDNA sequences encoding a putative benzodiazepine receptor ligand." DNA 6 (1): 71-79. GenBank Accession Number: p07107
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	C35	Webb, et al. 1987 "Bovine and human cDNA sequences encoding a putative benzodiazepine receptor ligand." DNA 6 (1): 71-79. GenBank Accession Number: m15888
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	C38	Webb, N. R., T. M. Rose, et al. (1987). "Bovine and human cDNA sequences encoding a putative benzodiazepine receptor ligand." DNA 6(1): 71-9.

* a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. _____, filed _____, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.

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